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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/252,384	06/01/1994	C. STEVEN MCDANIEL	TAMK145	3543
27922	7590	02/08/2006	EXAMINER	
C. STEVEN MCDANIEL MCDANIEL & ASSOCIATES, P.C. P.O. BOX 2244 AUSTIN, TX 78768			PAK, YONG D	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 02/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/252,384

Applicant(s)

MCDANIEL ET AL.

Examiner

Yong D. Pak

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 73-82 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 73-82 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This application is a continuation of 07/928,540, now abandoned, which is a divisional of 07/344,258, now abandoned.

Claims 73-82 are pending and are under consideration.

Response to Arguments

Applicant's amendment and arguments filed on November 7, 2005, have been fully considered and are deemed to be persuasive to overcome the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Sequence Compliance

Applicant is required to comply with the sequence rules by inserting the sequence identification numbers of all sequences recited within the claims and/or specification. It is particularly noted that the sequences in Figure 1 lack sequence identification numbers. See particularly 37 CFR 1.821(d).

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

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Claims 79-82 are rejected under 35 U.S.C. 101 because the claimed invention is directed to a non-statutory subject matter.

Claims 79-82, as written, are directed to non-statutory subject matter. Claims 79 and 81-82 could read on a host cell still attached to a host such as a human being. The claim does not make it clear that the cell, even though a recombinant cell, is an isolated cell. Claims that read on a human being are considered non-statutory. Furthermore, claims 79-82, as written, do not make it clear that the cell was indeed transformed with the claimed polynucleotides as it recites "contains". Examiner suggests amending claim 80 to recite "an isolated mammalian/eukaryotic cell transformed with..." to overcome the rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 75-77 and claims 78-82 depending therefrom are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 75-77 recite the phrase "the molecule". The metes and bounds of this term in the context of the above claims are not clear to the Examiner. It is not clear to the Examiner if the "nucleic acid molecule" is different from "the molecule". Examiner suggests amending the above claims to recite "wherein the nucleic acid molecule", for example.

Claims 80-81 and claim 82 depending therefrom are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 80-81 recite the term "contains". The metes and bounds of this term in the context of the above claims are not clear to the Examiner. It is not clear to the Examiner how a cell "contains" expression vectors. Examiner suggests amending the above claims to recite "cell transformed with the expression vector..", for example.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 73-82 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 73-82 are drawn to a polynucleotide having the nucleotide sequence of SEQ ID NO:1, the encoded polypeptide having the amino acid sequence of SEQ ID NO:2 and vectors and host cells comprising said polynucleotide. However, the polynucleotide encoding the polypeptide of SEQ ID NO:2 of claims 73-82 were not described in the application as originally filed nor in any of its parent applications. The specification as filed contains disclosure of a polynucleotide ("opd gene" of Figure 1)

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encoding an organophosphorus acid anhydrase which is different from the polynucleotide encoding the organophosphorus acid anhydrase of SEQ ID NO:2 submitted in the Sequence Listings filed on May 21, 2003, October 13, 2004, March 10, 2005 and November 7, 2005. Further, none of the polynucleotide sequence and the polypeptide sequences of SEQ ID NO:1 and 2 disclosed in the four Sequence Listings are identical to each other. Therefore, claims 73-82 contain new matter.

Given this lack of description of the polynucleotide encoding the polypeptide of SEQ ID NO:2 and vectors and host cells comprising said polynucleotide in the claims, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the inventions of claims 73-82 at the time of filing of the instant application.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov <<http://www.uspto.gov>>.

In response to the previous Office Action, applicants have traversed the above rejection.

Applicants argue that since the Sequence Listing previously filed was filed in error and the current Sequence Listing includes the corrected complete opd gene that was isolated and sequenced prior to the filing of the original parent application, claims 73-82 do not contain new matter. Examiner respectfully disagrees. Corrections of minor errors in the sequence may be possible based on resequenced sequences of deposited material. However, in the instant case, no such deposit of the sequenced

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material made in accordance with the requirements of 37 CFR 1.801 were disclosed in the specification as originally filed. Therefore, one of ordinary skill in the art would not recognize that applicants were in possession of the "complete opd gene" at the time the invention was filed.

Applicants also argue that one of skill in the art would have understood applicants to possess the claimed invention based on the method of isolating an opd gene in the specification and the nearly complete nucleotide and amino acid sequences as filed in the Sequence Listing of May 21, 2003. Examiner respectfully disagrees. Upon perusal of the specification, Examiner found no support for the above assertion. The specification is reiterated here for applicant's convenience.

SUMMARY OF THE INVENTION

The present invention provides an organophosphorus
15 detoxifying (opd) gene of the DNA sequence set forth in
Figure 1; a recombinant bacterial organophosphorus acid
anhydriase (OPA) enzyme derived from the opd gene; a
collection of expression vectors comprising the opd gene;
a collection of transformed cells comprising the opd gene
20 on an expression vector; and, transgenic organisms
comprising the opd gene on an expression vector.

The specification is very clear that the present invention is the "opd gene" and its encoded enzyme disclosed in Figure 1 and methods of producing such sequences. However, the nucleotide and amino acid sequences disclosed in Figure 1 are not the opd gene and its encoded polypeptide sequences filed in any of the Sequence Listings nor are they even partial sequences of the sequences filed in the Sequence Listings.

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The specification also does not teach that said opd gene of Figure 1 is a partial sequence of a complete opd gene. Further, MPEP 2163 states that:

"The claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence... A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process."

In the instant application, since there is no described or art-recognized correlation or relationship between the structure of SEQ ID NOs: 1 and 2 and its function nor a knowledge and level of skill in the art to permit one skilled in the art to immediately envisage SEQ ID NOs: 1 and 2 from the method described in the specification, claims 73-82 contains new matter.

Applicants also argue that because the chemical structure of the opd gene was almost complete, the molecule was available in a public depository and the specification discloses methods of isolating an opd gene, the specification provides more than adequate written description for SEQ ID NO:1 and 2.. Examiner respectfully agrees. The specification does not disclose any deposits of a plasmid or microorganism comprising the opd gene of SEQ ID NO:1. The "deposit" applicants are alluding to in the specification (page 7) is not a deposit of a plasmid or microorganism comprising the full length opd gene of SEQ ID NO:1, but a *Pseudomonas diminuta* or *Flavobacterium* sp. deposited with ATCC. Further, the specification does not disclose that the opd gene

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isolated is a partial one. In fact, the specification is very clear that the invention disclosed is a complete opd gene of Figure 1 and methods of making said gene. Therefore, a skilled artisan would not recognize that applicants were in possession of the inventions of claims 73-82 at the time of filing of the instant application.

Hence the rejection is maintained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 73-75 and 77-81 are rejected under 35 U.S.C. 102(e) as being anticipated by Serdar et al.

Claims 73-75 and 77-81 are drawn to a polynucleotide having the nucleotide sequence of SEQ ID NO:1, the encoded polypeptide having the amino acid sequence of SEQ ID NO:2 and vectors and host cells comprising said polynucleotide.

Serdar et al. (U.S. Patent No. 5,484,728 – form PTO-892) discloses a polynucleotide encoding a processed or mature anhydrase of 337 amino acids, consisting of a Met residue and residues 30-365 of the sequence in Figure 6, which has 100% sequence identity to the polynucleotide of SEQ ID NO:1 of the instant invention

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(See sequence alignment and claims 1-8 of Serdar et al.). Serdar et al. also discloses vectors and host cells comprising said polynucleotide (Columns 7-15 and claims 1-8). Therefore, the reference of Serdar et al. anticipates claims 73-75 and 77-81.

In response to the previous Office Action, applicants state that a declaration to antedate the reference will be filed. However, no such Declaration has been filed to date. Hence, the rejection is maintained until such declaration is filed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 76 and 82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Serdar et al. in view of Wong et al.

Claims 76 and 82 are drawn to a viral vector and a mammalian cell comprising a polynucleotide encoding SEQ ID NO:2.

Serdar et al. teaches a polynucleotide encoding SEQ ID NO:2, as discussed above.

The reference of Serdar et al. does not teach a viral vector or a mammalian cell comprising the polynucleotide.

However, viral vectors and mammalian host cells for the expression of heterologous proteins is well known. Wong et al. (U.S. Patent No. 4,849,355 – form PTO-892) discloses viral vectors and mammalian host cells comprising a heterologous polynucleotide (Columns 3-4 and claims 1-10).

Therefore, combining the teachings of Serdar et al. and Wong et al., it would have been obvious to one having ordinary skill in the art make a viral vector or mammalian host cell comprising the polynucleotide of Serdar et al. One of ordinary skill in the art would have been motivated to make such a construct to test expression of the claimed polypeptide as a heterologous protein in a mammal. One of ordinary skill in the art would have had a reasonable expectation of success since Wong et al. teaches how to make such a construct and successfully express heterologous proteins in mammals.

Therefore, the above references render claims 76 and 82 *prima facie* obvious to one of ordinary skill in the art.

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In response to the previous Office Action, applicants state that a declaration to antedate the reference will be filed. However, no such Declaration has been filed to date. Hence, the rejection is maintained until such declaration is filed.

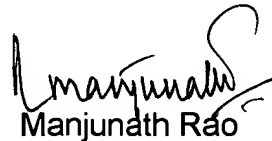
No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 571-272-0935. The examiner can normally be reached 6:30 A.M. to 5:00 P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone numbers for the organization where this application or proceeding is assigned are 571-273-8300 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Yong D. Pak
Patent Examiner 1652

A handwritten signature in black ink, appearing to read 'Manjunath Rao', with a stylized flourish at the end.

Manjunath Rao
Primary Patent Examiner 1652